GEORGIA INSTITUTE OF TECHNOLOGY — OFFICE OF CONTRACT ADMINISTRATION

PROJECT ADMINISTRATION DATA SHEET

[x] ORIGINAL [ ] REVISION NO. _____

Project No. E-24-611 GTRI/GTRx DATE 11/11/82

Project Director: Dr. Harrison M. Wadsworth School/Labx ISyE

Sponsor: US Department of Labor-OSHA

Type Agreement: P. O. No. B9F26482

Award Period: From 8/23/82 To 12/3/82 (Performance) 12/3/82 (Reports)

Sponsor Amount: Total Estimated: $ 10,000 Funded: $ 10,000

Cost Sharing Amount: $ _____ Cost Sharing No: _____

Title: Establishing Equivalency of Sampling Devices

ADMINISTRATIVE DATA OCA Contact Linda H. Bowman x4820

1) Sponsor Technical Contact:

2) Sponsor Admin/Contractual Matters:

Susan Harwood
Office of Carcinogen Standards
Directorate of Health Standards
Programs
OSHA
Washington, DC 20210

Defense Priority Rating: NA

Military Security Classification: NA

(or) Company/Industrial Proprietary: _____

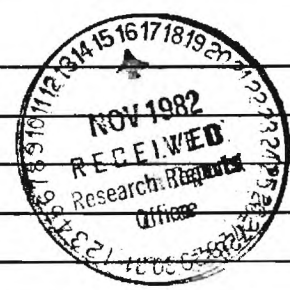
RESTRICTIONS

See Attached NA Supplemental Information Sheet for Additional Requirements.

Travel: Foreign travel must have prior approval – Contact OCA in each case. Domestic travel requires sponsor approval where total will exceed greater of $500 or 125% of approved proposal budget category.

Equipment: Title vests with Gov't; however, none proposed

COMMENTS:



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FORM OCA 4:781 (Rev 982)

GEORGIA INSTITUTE OF TECHNOLOGY OFFICE OF CONTRACT ADMINISTRATION

SPONSORED PROJECT TERMINATION SHEET

Date August 19, 1983

Project Title: Establishing Equivalency of Sampling Devices

Project No: E-24-611

Project Director: Dr. Harrison M. Wadsworth

Sponsor: U.S. Department of Labor - OSHA

Effective Termination Date: 12-3-82

Clearance of Accounting Charges: 12-3-82

Grant/Contract Closeout Actions Remaining:

- [X] Final Invoice ~~and Closing Documents~~ See revised Financial Data Sheet issued 1/31/83
- [ ] Final Fiscal Report
- [ ] Final Report of Inventions
- [ ] Govt. Property Inventory & Related Certificate
- [ ] Classified Material Certificate
- [ ] Other _____

Assigned to: ISyE (School/~~Laboratory~~)

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FORM OCA 10:781

SCHOOL OF INDUSTRIAL AND SYSTEMS ENGINEERING

GEORGIA INSTITUTE
OF TECHNOLOGY
ATLANTA, GEORGIA 30332

Revised Protocol for Establishing Equivalency of Sampling Devices

Submitted to

United States Department of Labor

OSHA

by

Harrison M. Wadsworth, Jr.
Georgia Institute of Technology
School of Industrial and Systems Engineering
Atlanta, Georgia 30332

and

Howard Rockette
University of Pittsburgh
Graduate School of Public Health
Pittsburgh, Pennsylvania 15261

Revised Protocol for Establishing Equivalency of Sampling Devices

1. Introduction

In December 1982 and January 1983 proposed protocols for establishing the equivalency of alternate cotton dust samplers to the vertical elutriator were submitted to OSHA. The December proposed protocol was by Dr. Wadsworth while that submitted in January was by Dr. Rockette. Since that time Drs. Wadsworth and Rockette have been working together in an attempt to validate both procedures and to establish a final single protocol. Simulation studies have been used in this effort. Details of the simulation studies are available from either author.

The protocol presented here is based on the two methods presented and the above mentioned simulation studies. The protocol has been discussed with members of the OSHA staff. It is believed by both authors that proper validation should be made with real data at some future time in order to understand more completely how the protocol will perform its intended function, i.e., serving as a procedure to be followed to evaluate the equivalency of air sampling devices for cotton dust.

2. Proposed Protocol

a. Samples to be taken. In order to ascertain equivalency it is necessary to collect a total of 100 samples from at least 10 sites in a mill. That is, there should be 10 replicate readings at each of 10 sites. The sites should represent dust levels which vary over the allowable range of 0.5 to 2 times the permissible exposure limit. Each sample requires the use of two vertical elutriators (VE's) and at least one but not more than

two alternate devices (AD's). Thus, the end result is 200 VE readings and either 100 or 200 AD readings. The 2 VE readings and the 1 or 2 AD readings at each time and site must be made simultaneously. That is, the two VE's and one or two AD's must be arranged together in such a way that they are measuring essentially the same dust levels.

b. Data averaging. The two VE readings taken at each site are then averaged. These averages are to be used as the 100 VE readings. If two alternate devices were used, their test results are also averaged. Thus, after this step is accomplished, there will be 100 VE readings and 100 AD readings.

c. Differences. For each of the 100 sets of measurements (VE and AD) the difference is obtained as the average VE reading minus the AD reading. Call these differences D_i. That is we have,

$$D_i = VE_i - AD_i, \quad i = 1,2,\ldots,100 \tag{1}$$

Next we compute the arithmetic mean and standard deviations of the differences, using equations (2) and (3), respectively.

$$\bar{X}_D = \frac{1}{N} \sum_{i=1}^{N} D_i \tag{2}$$

$$S_D = \frac{D_i^2 - \frac{(D_i)^2}{N}}{N-1} \tag{3}$$

where N = number of differences (100 in this case).

We next calculate the critical value as $T=KS_D$

where K = 1.87, based on 100 samples.

d. Equivalency test. The next step is to obtain the average of the 100 VE readings. This is obtained by equation (4)

$$\bar{X}_{VE} = \frac{1}{N} \sum_{i=1}^{N} VE_i \qquad (4)$$

where N again is the number of VE readings (100 in this case).

We next multiply 0.25 by $\bar{X}_{VE}$. If T $0.25\bar{X}_{VE}$, we can say that the alternate device has passed the equivalency test.

3. Analysis of Protocol

The protocol outlined above is such that we can be 95% confident that at least 90% of the measurements of the alternative device are within 25% of the corresponding VE reading. Simulation studies indicated that this test was such that 2.5% of the time the VE would reject itself.

APPENDIX

An example to illustrate the use of this protocol is as follows. The data shown use 100 hypothetical pairs of readings taken as described in the protocol.

Site 1

VE	AD	VE-AD
377	416	-39
377	418	-41
377	410	-33
377	420	-43
377	436	-59
377	423	-46
393	419	-26
393	417	-24
393	408	-15
393	401	-8

Site 2

VE	AD	VE-AD
393	385	8
426	381	45
426	361	65
426	397	29
426	399	27
405	397	8
446	381	65
415	392	23
372	390	-18
385	402	-17

Site 3

VE	AD	VE-AD
324	274	50
345	252	93
339	277	62
310	294	16
323	284	39
328	262	66
280	272	8
330	272	58
305	245	60
318	242	76

Site 4

VE	AD	VE-AD
271	240	31
306	219	87
325	255	70
274	256	18
314	262	52
299	275	24
309	298	11
302	241	61
372	351	21
415	364	51

Site 5

VE	AD	VE-AD
285	287	-2
294	288	6
290	286	4
229	243	-14
349	333	16
297	290	7
349	352	-3
313	295	18
381	442	-61
375	388	-13

Site 6

VE	AD	VE-AD
483	479	4
445	499	-54
334	398	-64
435	422	13
413	341	72
458	466	-8
433	474	-41
362	332	30
360	412	-52
332	429	-97

Site 7

VE	AD	VE-AD
335	278	57
325	372	-47
315	365	-50
307	292	15
292	361	-69
323	336	-13
217	250	-33
320	313	7
296	319	-23
413	405	8

Site 8

VE	AD	VE-AD
403	383	20
331	355	-24
360	396	-36
351	284	67
393	355	38
333	356	-23
349	336	13
464	475	-11
431	413	18
326	350	-24

Site 9			Site 10		
VE	AD	VE-AD	VE	AD	VE-AD
382	396	-14	545	510	35
410	319	91	440	490	-50
413	380	33	438	401	37
371	403	-32	452	409	43
242	382	-140	437	469	-32
291	358	-67	302	371	-69
385	331	54	391	355	36
356	391	-35	329	381	-52
327	371	-44	316	359	-43
391	371	20	394	375	19

The average and standard deviations of the differences are:

$$\bar{X}_D = 2.96$$

$$S_D = 44.99 .$$

The critical value, T, would be:

$$T = 1.87(44.99) = 84.13 .$$

The average of the 100 VE readings is 360.56. The equivalency test is that if $T \leq 0.25\ \bar{X}_{VE}$, we would assume equivalency of the devices. In this case since $T \leq 0.25(360.56) = 90.14$, we would conclude that the sampling devices are equivalent.

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Establishing Equivalency of Sampling Devices

Submitted to

United States Department of Labor

OSHA

by

Harrison M. Wadsworth, Jr.

Georgia Institute of Technology

School of Industrial and Systems Engineering

Atlanta, Georgia 30332

Contracting through

GEORGIA TECH RESEARCH INSTITUTE

December 1982

P.O. No. B9F26482
Project No. E-24-611

Establishing Equivalency of Sampling Devices

1. Introduction

Currently the Occupational Safety and Health Administration of the United States Department of Labor specifies a procedure for measuring cotton dust in the atmosphere of a cotton mill. This standard states minimal dust levels as measured by the vertical elutriator cotton dust sampler. It further states in clause 29CFR 1910.1043(D)[1]

"(ii) The sampling device to be used shall be either the vertical elutriator cotton dust sampler or a method of equivalent accuracy and precision.

(iii) If an alternative to the vertical elutriator cotton dust sampler is used, the employer shall establish equivalency by demonstrating that the alternative sampling devices:

(a) Collect respirable particulates in the same range as the vertical elutriator (approximately 15 microns);

(b) Replicate exposure data in side-by-side field comparisons; and

(c) Are equivalent within an accuracy and precision range of plus or minus 25 percent for 95 percent of the samples over the range of 0.5 to 2 times the permissible exposure limit."

This section does not include enough criteria for the equivalency of an alternate device to be determined. The protocol cannot establish a means of ascertaining a measure of confidence that truly 95 percent of all such pairs of readings that may be obtained would be within 25 percent of each other. The purpose of this report is to propose a protocol which will be statistically sound and, by means of which, the equivalency of any other device to the vertical elutriator (VE) may be determined.

This protocol should be simple and straightforward to use. It should also eliminate the implied ambiguities present in the current protocol.

2. General Principles

Many factors contribute to the variability of a test procedure, for example,

(a) the operator

(b) the instruments used

(c) the calibration of the equipment

(d) the environment.

In the case of cotton dust, all of these variables exist and therefore the equivalency of sampling devices must be established over a range of the variables. It would be expected that the variability will be larger when different operators are involved or different instruments involved. Therefore, in order to establish equivalency, several instruments of each type must be used. Since operator differences are not required to establish equivalency, different operators should not be used or, if they must, they must all be adequately trained. It is important that equivalency be established over the stipulated range of dust levels, i.e., 0.5 to 2 times the allowable level.

The current protocol states the equivalency should be established for precision and accuracy. These terms are not synonomous. Precision deals with the repeatability of readings taken under the same condition, i.e., the same operator, equipment, time, environment, etc. Accuracy deals with the correctness of the measurements. Thus two devices may both be accurate (give the correct readings on the average) but differ in precision. In order to determine the equivalency of a proposed device to the VE, a measure of the precision

of both the VE and the proposed device must be established. If a proposed device is consistently inaccurate, so that it has a constant bias, this may be corrected. However, if it is less precise, correction becomes much more difficult.

In order to establish equivalency, a measure of the variability of the proposed device and the VE must be used. This could be either the standard deviation or the range. For the purposes of this protocol the standard deviation will be used.

For estimating the precision of a sampling device, it is useful to think of each test result as the sum of three components:

$$y = m + b + e$$

where m is the general average, b is a term representing the difference between devices and e is a random error occuring in every test. In this model, m is the average level of the test, i.e., the dust level at which the test was made. The true dust level, μ, may differ from that of m. The bias of the device is the difference between m and μ. Different locations in a mill will result in different values of μ. Since the true level, μ, is unknown, we must use m as an estimator of the parameter, μ, of the model. For the purposes of this protocol m will be the average level indicated by the VE.

The term b in the model represents the effect of using a particular sampling device. This term is a random variable with two components, i.e.,

$$b = b_0 + b_s.$$

The random component is b_0 while b_s is a systematic component. If both devices are truly equivalent b_s will be zero. The random component can be assumed to be approximately normally distributed. The variance of b would be caused by variations in other factors such as humidity, temperature, cotton blends, etc. The variance of b will be called the between machine variance, σ_L^2. This variance includes the random and systematic components. It is assumed that the systematic component is constant for a given pair of devices, therefore it will not affect σ_L^2.

The error term, e, may also be assumed to be approximately normal. With a single sampling device in a single location it represents differences among replicate readings. The term e is often called repeatability and the variance will be termed σ_e^2. More specifically, repeatability is the value below which the absolute difference between two test results obtained under the same conditions may be expected to lie with a specified probability. This probability is taken here to be 95%. This definition is consistent with ISO 5725-1981[2]. The 95% probability level is also consistent with the intent of the current protocol as described in the introduction. The symbol r represents critical differences at the 95% probability level for two single test results obtained under repeatability conditions.

Using these definitions, we may describe repeatability as,

$$r = 2\sqrt{2}\ \sigma_e = 2.83\sigma_e$$

Until actual values of σ_e^2 can be obtained, estimates must be used which come from the sample data. Procedures for obtaining these estimates will be discussed later in this report. Such estimates for the VE and the candidate device should not be significantly different. Further experimental work may

be conducted to determine if σ_e^2 for the VE can be established. If this can be done, this protocol would be simplified. Details of this experimental work will be discussed later in this report.

In summary, if two different types of dust sampling devices are set up side by side in such a manner that they are both measuring air with essentially the same dust level, a pair of test determinations (one from each device) should be within $r = 2.83\sigma_e$ of each other. If the measurements are not within this range they are determined to be significantly different and, on the assumption that the VE is correct, the other device would be rejected.

When several readings are obtained from each sampling device the average of the readings from each device should be obtained. Before proceeding, however, the readings should be checked for outliers as discussed in the section of outliers. If there are no outliers, the critical difference between the two averages is,

$$C_r D = 2\sqrt{(\frac{1}{n_1}+\frac{1}{n_2})\sigma_e^2}$$

where n_1 and n_2 are the two sample sizes,

3. Determination of Data

It is recommended that at least five vertical elutriators and five alternative devices be used in at least ten different mill areas which would result in differences in dust levels such that the range of 0.5 to 2.0 times the allowable level is covered. If repeatability variances are determined for the VE, only one VE would be necessary at each location.

If it is impossible to obtain this many measuring devices or, because of space or other limitations, to use this many simultaneously, fewer devices may

be used over several days, such that the same number of total readings of each device will be obtained. In doing this, care must be taken so that the different days have approximately the same overall dust level. The same product should be run each day. It is also important that the same number of each type of devices are run each day in order to get equivalent pairs of readings.

Data will be obtained from each location on each sampling device and a table similar to Table 1 completed. In Table 1, VE stands for the reading for the vertical elutriator and AD stands for the reading for the alternate device.

Differences and ratios of the pairs of readings will be obtained and inserted in the appropriate place in Table 1. The mean and standard deviation of the readings for each instrument at each location will then be obtained and inserted in the appropriate place in the table. These will be obtained by means of equations (1) and (2) or (3) and (4).

$$S_{ij} = \sqrt{\frac{1}{n_{ij}-1} \sum_{k=1}^{n_{ij}} (y_{ijk}-\bar{y}_{ij})^2}$$

$$= \sqrt{\frac{1}{n_{ij}-1} \left[\sum_{k=1}^{n_{ij}} y_{ijk}^2 - \frac{1}{n_{ij}} \left(\sum_{k=1}^{n_{ij}} y_{ijk} \right)^2 \right]} \qquad (1)$$

$$\bar{y}_{ij} = \frac{1}{n_{ij}} \sum_{k=1}^{n_{ij}} y_{ijk}, \qquad i=1,2;\ j=1,\ldots,q \qquad (2)$$

With 10 locations and 5 readings per device per location, equations (1) and (2) become,

Table 1. Data Table

Location	Replicate	VE	AD	AD-VE	AD/VE
1	1				
	2				
	3				
	4				
	5				
	$\bar{y}_{i1}$				
	$\bar{s}_{i1}$				
2	1				
	2				
	3				
	4				
	5				
	$\bar{y}_{i2}$				
	s_{i2}				
----------	----------				
q	1				
	2				
	3				
	4				
	5				
	$\bar{y}_{iq}$				
	s_{iq}				

$$S_{ij} = \sqrt{\frac{1}{4} \sum_{k=1}^{5} (y_{ijk} - \bar{y}_{ij})^2}$$

$$= \sqrt{\frac{1}{4}\left[\sum_{k=1}^{5} y_{ijk}^2 - \frac{1}{5} \left(\sum_{k=1}^{5} y_{ijk} \right)^2 \right]} \qquad (3)$$

$$\bar{y}_{ij} = \frac{1}{5} \sum_{k=1}^{5} y_{ijk}, \qquad i=1,2;\ j=1,2,\ldots,10 \qquad (4)$$

4. Analysis of Ratios

As indicated in the previous section, ratios of each pair of readings are obtained. The current OSHA protocol states that 95% of all readings should be within 25% of the VE. This means that these ratios should be between 0.75 and 1.25.

In the last column of Table 1, the smallest and largest ratio should be obtained. Based on 50 such ratios and considering these 50 to be a random sample from an infinite population of such ratios, we may be 70% certain that 95% of all such ratios are between the smallest and largest ratio among the 50. Larger samples would be required to increase the confidence. For example, Table 2 indicates the confidence obtained for sample sizes from 50 to 95.

Table 2

n	Confidence	n	Confidence
50	70%	75	90%
55	72	80	91
60	80	85	93
65	84	90	94
70	86	95	95

If the smallest ratio is larger than 0.75 and the largest is less than 1.25, it would seem that this condition has been met. If one ratio is

outside the range of 0.75 to 1.25, a similar tolerance interval could be used using the second largest and the second smallest ratio. For 50 ratios this would yield a confidence of only 32% that 95% of all such ratios are between these two ratios. If we use the third largest and third smallest the confidence would be reduced to 12%. For a sample of 90 such ratios, the corresponding confidence coefficients would be 66% and 30% respectively.

5. Analysis of Location Means and Variances

Using equations (1) and (2) or (3) and (4) the mean and standard deviation of each device at each location will be determined. The two devices should be checked for the same precision at each location. This may be done by the usual F-test for the ratio of two sample variances. That is, for each location, j, let S^2_{sj} be the smaller of the two variances and $S^2_{\ell j}$ be the larger. Then compute the statistics,

$$F_j = \frac{S^2_{\ell j}}{S^2_{sj}}, \quad j=1,\ldots,q \tag{5}$$

If any $F_j \geq 6.39$ (based on 5 replicates for each device), reject the equal precision assumption for that location (dust level). If this occurs, the data in the sample with the larger variance should be examined for an outlier using the procedures in the section on outliers. If an outlier is found to be due to a faulty reading, the reading should be corrected. If not, we must conclude the two devices do not have equal precision.

If none of the F_j's exceed the critical value of 6.39, we should next pool the variances for the VE. Before doing this, we must determine if any of them are significantly different. ISO 5725-1981[2] recommends this be done using

Cochran's test for maximum variance. The test statistic, C, is given by equation (6),

$$C = \frac{S^2_{max}}{\sum_{j=1}^{q} S^2_{1j}} \qquad (6)$$

where S^2_{max} is the largest of the VE variances and S^2_{1j} is the variance of the VE readings for the jth location. If C exceeds the critical value given in Table 3 (based on variances from equal samples of 5 replications each), the locations do not have equal variances. That is, the VE does not perform with equal precison at each dust level.

Table 3. Critical Values for Cochran's Test Based on n=5 and γ=.95

No. of Locations	$C_{.95}$	No. of Locations	$C_{.95}$
5	0.544	13	0.271
6	0.480	14	0.255
7	0.431	15	0.242
8	0.391	16	0.230
9	0.358	17	0.219
10	0.331	18	0.209
11	0.308	19	0.200
12	0.288	20	0.192

If standards for the precision of the VE are later determined, this step may be omitted and the standard value for σ^2_e for the VE used. However, since this has not yet been done, an estimate for this parameter must be determined by averaging over the locations. Thus the estimate of σ^2_e for the VE is found by use of equation (7) or (8)

$$s_e^2 = \frac{\sum_{j=1}^{q} (n_{1j}-1)s_{1j}^2}{\sum_{j=1}^{q} n_{1j} - q} \tag{7}$$

If there are q=10 locations and each has 5 replicates, equation (7) becomes,

$$s_e^2 = \frac{1}{10} \sum_{j=1}^{10} s_{1j}^2 \tag{8}$$

The critical difference (or repeatability) value for the VE may now be established as,

$$CrD_{.95} = 2\sqrt{(\tfrac{2}{n})s_e^2} \tag{9}$$

Again, for n=5, this is

$$CrD_{.95} = 2\sqrt{(0.4)s_e^2} \tag{10}$$

This statistic, $CrD_{.95}$, is the absolute difference of the means of two samples of size n which should occur no more than five percent of the time. That is, the difference in the means, $|\bar{y}_{1j}-\bar{y}_{2j}|$, for each location should be smaller than the $CrD_{.95}$ at least 95% of the time if the two devices have the same accuracy.

6. Test for Outliers

Several tests for outliers are available in the statistical literature, ISO 5725-1981[2] recommends the Dixon Outlier Test. This test requires the observations in each sample (same instrument, same location) be first ordered

from smallest to largest. Then, for sampls of size 5, the statistic Q is calculated as the larger of,

$$Q = \frac{y_{(2)} - y_{(1)}}{y_{(5)} - y_{(1)}} \quad \text{or} \quad \frac{y_{(5)} - y_{(4)}}{y_{(5)} - y_{(1)}} \tag{11}$$

where

$y_{(1)}$ = smallest observations

$y_{(2)}$ = next smallest observation

etc.

The 5% and 1% critical values of Q are, respectively, 0.710 and 0.821. If Q is less than 0.710 we conclude there are no outliers. If it is between 0.710 and 0.821, it is questionable and the data should be examined carefully. If $Q > 0.821$, there is an outlier present.

7. Establishing a Standard Repeatability Variance for the VE

The repeatability variance, σ_e^2, may be determined for the vertical elutriator by means of separate study. This study would use several such instruments in a large range of dust conditions in several mills. The study would determine if a standard value of σ_e^2 could be established for the VE.

If successful, this standard value could then be used for the repeatability variance for the tests described in Section 5 of this report. The protocol could then require one VE with five alternate devices. The tests outlined in Section 5 would be modified to take this into account. For example, the test in Equation (5) for equal variances would then become a one sample test, testing to see if the variance of the alternative device is different from

the standard repeatability variance. This would be done by means of Equation (12), the results of which would be compared to a chi-square distribution.

$$X^2 = \frac{(n_{2j})s_{2j}^2}{\sigma_e^2} \quad , \; j=1,\ldots,q \tag{12}$$

where

n_{2j} = number of observations with alternative device at location j

s_{2j}^2 = variance of alternative device at location j

The test in Equation (6) and the pooling of variances in Equations (7) and (8) would no longer be needed. The standard repeatability variance, σ_e^2, would be used in Equations (9) and (10).

Great care must be used in fixing this standard variance. In fact, the suggested research may indicate a different variance to be needed for different dust levels. If so, the protocol would still be considerably simplified.

8. Conclusions

To conclude this report a summary of the protocol recommended is as follows:

1. Take side-by side readings at at least 10 sites in a mill using 5 replicates per site for each sampling device.
2. Find the ratio of the alternate device to the VE for each replicate.
3. Find the smallest and largest value of these ratios. Conclude (for N=50) that we are 70% confident that 95% of such ratios will be within these two values.
4. Are these two extreme ratios between 0.75 and 1.25? If so, we may conclude that overall accuracy is met.
5. Compute the mean and variance for each position and each device.

6. Compare the variances at each position using the F-test (equation 5).
7. Compare the variances for the VE at each location using Cochran's test (equation 6).
8. Pool the variances for the VE.
9. Compute $CrD_{.95}$ for the differences in means.
10. Compare the differences in means at each location with the critical difference determined in Step 9. If any of these differences exceeds $CrD_{.95}$, conclude the devices are giving different average readings.

To conclude that an alternative device is acceptable, it should meet the tests in Steps 4, 6 and 10.

References

1. U.S. Department of Labor - OSHA, "Occupational Exposure to Cotton Dust Final Mandatory Occupational Safety and Health Standards, Part III", June 23, 1978.

2. International Organization for Standardizations, ISO 5725-1981, "Precision of Test Methods - Determination of Repeatability and Reproducibility by Inter-Laboratory Tests".